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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,653	06/05/2000	David V. Sangar	UTSG.231US	8912

7590 10/21/2002

Fubright & Jaworski LLP  
600 Congress Avenue Suite 2400  
Austin, TX 78701

EXAMINER
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SCHEINER, LAURIE A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/21/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/587,653

Applicant(s)

Sangar et al.

Examiner

Laurie Scheiner

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1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 5, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 56 is/are pending in the application.
- 4a) Of the above, claim(s) 1-18, 22-26, and 34-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21 and 27-33 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Claims 1-18, 22-26 and 34-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7. It is noted that newly added claims 51-55 are also withdrawn from consideration as being drawn to a nonelected invention since the methods therein are ultimately limited to nucleotides which differ in structure from the nucleotides of the elected method claims.

It is noted that applicants state at page 3 of their response that claims 51-55 were withdrawn as being non-elected species. The examiner notes that applicants have erred in their statement since the claims were withdrawn as being drawn to a non-elected **invention**. The traversal by applicants of the withdrawal of claims 51-55 is acknowledged. However, the traversal is not persuasive since applicants' argument is based on purported structure similarity which would result in no additional examiner search requirement. The examiner contends, however, that the respective structures do in fact differ and applicants' remarks are both presumptive, with respect to search burden, and incorrect since an additional search of SEQ ID NO:2 would be required. The examiner has also determined that a species requirement is inappropriate in the instant case due to structural differences between the sequence identifiers to which the claims in question are limited. As such claims 51-55 are withdrawn from further consideration. The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 19-21, <sup>and 56</sup> and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant's arguments filed July 17, 2002 have been fully considered but they are not persuasive.

With respect to the rejection of claims under 35 U.S.C. 112, second paragraph, applicants contend that one of ordinary skill in the art would be able to produce a virus by the steps outlined in claim 19, and described on pages 23-26 and 31-37 of the specification. The examiner contends that a simple assertion by applicants cannot overcome the lack of correlation between that which is taught in the specification and that which is claimed. Moreover, it seems that applicants have improperly addressed a second paragraph rejection with an enablement argument. It is noted that an enablement rejection might, or might not, be appropriate if it could be determined what applicants are claiming. That is, applicants claim a method of producing a virus by introducing into a host cell a recombinant viral expression construct comprising a polynucleotide encoding a 3' sequence of GBV-B. One cannot determine that which applicants intend. Is a recombinant GBV-B intended, a recombinant GBV-B/HCV chimera, a viable IRES chimera? Applicants appear to confuse an expression construct with a viable virus. Again, It is noted that a scope of enablement rejection would have been made if it were clear that a method for making **any** viable virus was intended. However, the examiner cannot determine what is intended. What sequences, and in what gene order/and frame, in addition to the 50 contiguous nucleotides from SEQ ID NO:1 are intended? What virus is intended? The claims read on a method of making any virus having a GBV-B 3' sequence. Do applicants intend a method of making a recombinant HIV/GBV-B chimera? Again, it is impossible to determine that which

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applicants consider to be their invention. The pending claims do not in anyway correspond to what is taught in the specification; further resulting in an inability to determine the metes and bounds of the claims. Applicants contend that they have provided SEQ ID NO:1 and methods of constructing an infectious GBV-B clone, a full length clone and the nucleotide sequence of the cloned GBV-B cDNA. The examiner contends that applicants do not claim a method of making an infectious GBV-B clone, nor do they claim a method of making a full length clone and the nucleotide sequence of the cloned GBV-B cDNA. Applicants claim a method of making a virus. As such, applicants' claims are drawn to making any virus so long as at least 50 contiguous nucleotides from SEQ ID NO:1 are included in some unknown insertion point, in some unknown vector. Again, a virus *per se* cannot be produced by a 3' portion of a viral genome. That is, an intact virus can be produced by expression of the entire viral genome only, providing that appropriate viral early proteins are available for processing. Expression of viral genes is not the same as making or replicating virus. Again, in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), the court pointed out that before the claimed subject matter could properly be compared to the prior art, it was essential to know what in fact the claims did cover.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will


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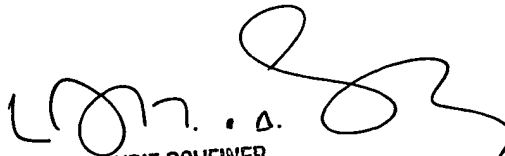
be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

  
Laurie Scheiner/LAS  
October 19, 2002

  
LAURIE SCHEINER  
PRIMARY EXAMINER